

Article - Health Occupations

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§12-6C-10.

(a) A person who is engaged in the wholesale distribution of a prescription drug that leaves, or has ever left, the normal distribution channel shall provide, before each wholesale distribution of the prescription drug, a pedigree to the person who receives the prescription drug.

(b) A retail pharmacy or pharmacy warehouse shall comply with the requirements of this section only if the pharmacy or pharmacy warehouse engages in the wholesale distribution of a prescription drug in the State.

(c) (1) To be considered part of the normal distribution channel, a wholesale distributor, a manufacturer's exclusive distributor, and a manufacturer's third party logistics provider also must be an authorized distributor of record.

(2) Notwithstanding paragraph (1) of this subsection, a pharmacy warehouse that is not an authorized distributor of record shall be considered part of the normal distribution channel.

(d) Each person who engages in the wholesale distribution of a prescription drug, including repackagers but excluding the original manufacturer of the finished form of the prescription drug, who is provided a pedigree for the prescription drug and attempts to further distribute the prescription drug, shall authenticate, before any distribution of the prescription drug occurs, that each transaction listed on the pedigree has occurred.

(e) The pedigree shall include:

(1) All necessary identifying information relating to each sale in the chain of distribution of the prescription drug from the manufacturer or the manufacturer's third party logistics provider, co-licensed partner, or manufacturer's exclusive distributor, through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the prescription drug, including:

(i) The name, address, telephone number, and if available, electronic mail address, of each owner and each wholesale distributor of the prescription drug;

(ii) The name and address of each location from which the prescription drug was shipped, if different from the owner's;

(iii) Transaction dates; and

(iv) Certification that each recipient has authenticated the pedigree;

(2) The name of the prescription drug;

(3) The dosage form and strength of the prescription drug;

(4) The size of the container;

(5) The number of containers;

(6) The lot number and National Drug Code of the prescription drug;

and

(7) The name of the manufacturer of the finished dosage form.

(f) Each pedigree for a prescription drug shall be:

(1) Maintained by the purchaser and the wholesale distributor for 3 years from the date of sale or transfer; and

(2) Available for inspection or use within 5 business days on request of the Board, the Board's designee, or an authorized law enforcement officer.

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